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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/740,694	12/22/2003	Murty N. Arimilli	18477.031 / 259.PC2	1095

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ARNOLD & PORTER LLP  
ATTN: IP DOCKETING DEPT.  
555 TWELFTH STREET, N.W.  
WASHINGTON, DC 20004-1206

EXAMINER
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HUMPHREY, LOUISE WANG ZHIYING

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/740,694

Applicant(s)

ARIMILLI ET AL.

Examiner

Louise Humphrey, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-180 is/are pending in the application.
- 4a) Of the above claim(s) 4-29,34-61,66-92,97-122 and 126-180 is/are withdrawn from consideration.
- 5) ☒ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,30-33,62-65,93-96, and 123-125 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/29/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

The Office acknowledges the receipt of Applicant's election, filed on 22 December 2005.

#### ***Election/Restrictions***

Applicant elects Group I, claims 1-3, 29-33, 61-65, 92-96, and 122-125, and the species of cell culture in claim 31, with traverse.

The traversal is on the grounds that there is no serious burden in examining the different Inventions and species together. Applicant's traversal is unpersuasive for the following reasons:

While a search of the prior art for one Group (or species) may overlap with that of another group (or species), the searches are not co-extensive and thus would be an undue burden on Office resources even if the Groups were placed in the same class and subclass. Examiner has established the serious search burden by the explanations of the distinctness between the different Inventions in the previous Office Action.

Contrary to Applicant's position, Applicants' citation of M.P.E.P. §803 only supports the Examiner's position in the prior Office action that "because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, and require non-coextensive literature searches even though in some cases the classification is shared, restriction for examination purposes as indicated is proper" [emphasis added]. While a search of the prior art for one Group may overlap with that

of another group, the searches are not co-extensive and thus would be an undue burden on Office resources even if the Groups were placed in the same class and subclass. The PTO classification is merely an administrative convenience and is not dispositive of relatedness of applications.

Applicants' contention that the examination of the application would be handled most expeditiously by treating all the species claims as a single entity is not supported by any evidence or reasons.

Since Applicants only assert that they disagree and but do not support their position with any further rationale, the restriction among the different products that may be used in the claimed methods is maintained.

It is noted that Applicant is no longer entitled to the rejoinder of the process claims with the product claims in light of *In re Ochiai* and *In re Brouwer* because Applicant has elected the process invention. See M.P.E.P. §821.04.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-180 are pending. Claims 4-29, 34-61, 66-92, 97-122, and 126-180 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in the reply filed on 22 December 2005.

Claims 1-3, 30-33, 62-65, 93-96, and 123-125 are examined in the instant application and read to the species of a cell culture environment.

***Information Disclosure Statement***

An initialed and dated copy of Applicant's IDS form 1449, filed 29 June 2005, is attached to the instant Office action.

***Specification***

The disclosure is objected to because of the following informalities: the term "GS-7340" is misspelled as "GS-GS-7340" in line 22 on page 1691. Appropriate correction is required.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. §112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30-33, 62-65, 93-95, and 123-125 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims employ the enzyme, GS-7340 ester hydrolase, which is an arbitrary name that is meaningless to one skilled in the art in the absence of recitations of any identifying characteristics such as amino acid or nucleotide sequence, size, molecular weight,

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structure, and isoelectric point. Moreover, the term GS-7340 has already been used in prior art to name a prodrug for PMPA, a nucleoside analog inhibitor. See below. The name GS-7340 ester hydrolase can be understood as that this enzyme specifically hydrolyzes GS-7340 or that this enzyme shares the same properties as the prodrug compound GS-7340. Since the specification does not define the term or distinguish it from the prodrug, recitation of GS-7340 ester hydrolase is indefinite.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 96 are rejected under 35 U.S.C. §102(b) as being anticipated by Eisenberg *et al.* (2001).

The instant claims are directed to a method for identifying a candidate compound as a suitable pro-drug, comprising: (a) providing the candidate compound having an esterified phosphonate group or an esterified carboxyl group; (b) contacting the candidate compound with an extract capable of catalyzing the hydrolysis of a carboxylic ester to produce a metabolite compound; and (c) identifying the candidate compound as a suitable pro-drug if the metabolite compound has a phosphonic acid group instead of the esterified phosphonate group of the candidate compound, or a carboxylic acid group instead of the esterified carboxyl group of the candidate compound.

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Eisenberg *et al.* teach a method for evaluating whether GS-7340 is a suitable prodrug of PMPA. The metabolites of GS-7340 and PMPA, respectively, are analyzed and compared in peripheral blood mononuclear cells (PBMCs). See the entire document. The purpose of this method is to screen for a prodrug that is selectively hydrolyzed in target cells (page 1093, second paragraph). Eisenberg *et al.* further point out selective intracellular enzymatic hydrolysis of the prodrug candidate, GS-7340, in the PBMC extracts. See Conclusions.

Thus, claims 1-3 and 96 are anticipated by Eisenberg *et al.*

### ***Remarks***


Claims 30-33, 62-65, 93-95, and 123-125 are apparently free of prior art of the record. The prior art of Eisenberg *et al.* teaches the enzyme activity inside PBMC extracts but does not fairly suggest how to isolate the enzyme, GS-7340 ester hydrolase, from PBMCs.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D., whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902.

Louise Humphrey, Ph.D.  
Patent Examiner  
19 January 2006

  
**JEFFREY STUCKER**  
**PRIMARY EXAMINER**